



DEPARTMENT OF HEALTH & HUMAN SERVICES

MDR 4111

Public Health Service

HFI-35

COPY 3/6/97

April 21, 1997

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell, WA 98041-3012

Telephone: 206-486-8788  
FAX: 206-483-4996

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 97-13

Robert R. Bender, Vice President/Plant Manager  
Montana Merchandising, Inc.  
P. O. Box 907  
Sollid Road & Dakota Street  
Conrad, Montana 59425

**WARNING LETTER**

Dear Mr. Bender:

The Food and Drug Administration (FDA) recently conducted an inspection of your firm's facility located in Conrad, Montana, on 1/30-31/97 and 3/6/97.

During the inspection, our investigator noted serious violations of the Federal Food, Drug, and Cosmetic Act (the Act), in that food was being held under insanitary conditions, whereby it may have been contaminated with filth. Specifically, a lot consisting of approximately [REDACTED] pound totes of oat flour was found to have extensive rodent and insect activity associated with it. These and other adverse conditions were reported to Robert R. Bender on the FDA-483 (copy enclosed) issued at the conclusion of the inspection. Samples collected during the inspection were analyzed with laboratory confirmation of the rodent and insect filth. A report of this analysis was provided to you. Food held under such conditions is adulterated within the meaning of Section 402 (a)(4) of the Act.

As the most responsible official at the firm, it is your responsibility to assure that your facility is operated in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected but that adequate policies and procedures are implemented to prevent a recurrence of these problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies that may be present at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

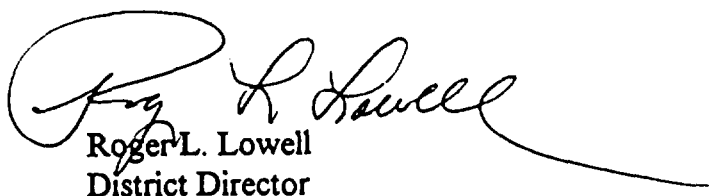
You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

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Robert R. Bender, Vice President/Plant Manager  
Montana Merchandising, Inc.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, P.O. Box 3012, Bothell, WA 98041-3012, Attention: Robert L. Wesley, Compliance Officer.

Sincerely,



Roger L. Lowell  
District Director

Enclosure  
FDA-483